# Research Proposal for IEC-PhD Research

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**PROJECT PROPOSAL**

**TITLE-** To comparatively evaluate the physical properties of different modifications of glass ionomer cement in primary dentition: an ex-vivo study.

**INTRODUCTION**

Wilson and Kent developed glass-ionomer cement (GIC) in 1969 after realizing the advantage of fluoride release in the silicate cements. [1] They are biocompatible and are commonly used for minimal intervention procedures like atraumatic restorative treatment. [2]

GIC is a clinically active restorative material commonly used by dental professionals for pediatric patients across the globe. This is due to some inherent and unique properties like continuous fluoride release, biocompatibility, and chemical adhesion to the tooth enamel, dentine and composite. [3] Use of GIC is also recommended in pediatric patients due to its excellent properties like low toxicity, ability of the material for regeneration of hard tissues and good adhesion to moist tooth structure.

However the various disadvantages associated with its use have decreased its performance. They are brittleness, sensivity to moisture, porosity resulting in inferior mechanical properties. [2]

In order to increase its clinical performance GIC has been reinforced with metal powders, modified with resin and incorporated with zirconia fibers, bioceramics and hydroxyapatite powder.[2]

Several studies done in the past concluded that addition of biocompatible materials improve the physical properties of glass ionomer cement. Modifications in both the powder and /or liquid components of commercially available GIC s have shown substantial changes in the physical properties of the cement.

There is a huge scope for application of novel biomaterials in pediatric patients and the quest for suitable modification of GIC continues.

After extensive exploration of literature, it has been found that no such study exists which compared the physical properties in the commercially available resin-modified GIC and newer modifications of GICs using primary teeth. Hence, the present in vitro study was undertaken.

**REVIEW OF LITERATURE**

1. **Kirthika N et al** conducted a study to evaluate the mechanical properties, fluoride levels and adhesion of bacteria of conventional GIC after the inclusion of different chemicals. Custom-made molds were used for specimen were prepared using custom-made molds and universal testing machine was used for evaluation of compressive and flexural strength. Erichrome cyanide reagent was used to estimate fluoride release, utilising UV-spectrophotometry. Bacterial adhesion was evaluated using calorimetry. It was found that the inclusion of some chemicals improved the resistance of conventional glass -ionomer cement, whereas MDPB enhanced the resistance of conventional glass-ionomer cement to bacterial adhesion. [4]
2. **Patel A et al** evaluated chitosan (CH)-incorporated resin modified glass ionomer cement for fluoride release and adhesive bond strength. It was found that inclusion of chitosan(CH) in resin modified glass ionomer cement causes increased fluoride release, but does not affect the bond strength. [2]

3. **Lami Al-Taee et al** evaluated effect of inclusion of reactive glass additives and modes of mixing on the physical properties of several glass-ionomer cements. They concluded that statistically significant effect was noted in the physical properties of the selected GICs-RMGICs when reactive glass additives were included in the cement and also due to the mode of mixing. [5]
4. **Jaidka S et al** evaluated the bond strength, diametral tensile and compressive strength of GIC type IX, chlorhexidine, and triclosan included GIC. They found that the following mechanical properties of 0.5% triclosan and 0.5% chlorhexidine-GIC were comparable to type IX GIC suggesting that they are viable options for use in pediatric dentistry.[6]
5. **Bali P et al** conducted a study to find out the influence of the inclusion of 8% hydroxyapatite to tradional GIC on its antibacterial activity and compressive strength . They concluded that traditional GIC showed increase in the antibacterial activity after the inclusion of 8% hydroxyapatite.[7]

## AIMS AND OBJECTIVES

AIM: Comparative evaluation of the physical properties of different modifications of glass ionomer cement in primary dentition: an ex-vivo study.

## OBJECTIVES:

1. To evaluate the physical properties of different modifications of glass ionomer cement namely GIC Type IX, Giomer and Zirconomer and Resin-modified Glass Ionomer Cement (RMGIC) used for restoring carious primary teeth.
2. To compare the physical properties of GIC Type IX, Giomer and Zirconomer with resin-modified glass ionomer cement (RMGIC) in terms of fluoride release, compressive strength, flexural strength, wear resistance, and marginal integrity.

## MATERIALS AND METHODOLOGY

The present research will be accomplished in the Pediatric and Preventive Dentistry Department, Faculty of Dentistry and Chemistry Department, Jamia Millia Islamia, New Delhi in collaboration with Metallurgical Laboratory after getting clearance from IRRC and IEC of Jamia Millia Islamia.

**Study Design:** This pilot study shall be an ex-vivo study. The criteria for inclusion and exclusion of samples are as follows:

**Inclusion criteria:**

- Freshly extracted primary teeth with one or two surface caries involvement and roots at different stages of resorption in a child 8-13 years of age.
- Primary molars extracted for orthodontic purposes i.e. serial extraction.

**Exclusion criteria:**

- Deeply carious molars and molars with exposed pulps.

- Grossly carious primary molar teeth will be excluded.
- Hypoplastic or hypomineralized primary teeth will be excluded.
- Primary teeth with fracture lines were excluded.
- Primary teeth with internal resorption will be excluded.

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**ARMAMENTARIUM**

1. Universal testing machine (Instron model)
2. UV spectrophotometry
3. Stereomicroscope
4. 2% Methylene blue dye
5. Chemicals for artificial saliva
6. Color indicator dye for fluoride release

**MATERIAL/ EQUIPMENTS FOR THE STUDY**

**For selection and storage of teeth:**

1. Normal saline
2. Distilled water
3. Thymol
4. Ultrasonic scaling unit with scaler tips

**For cavity preparation**

1. Airotor (NSK Handpiece)
2. No. 245 bur and No. 330 bur (SS White, Japan)

**For restoration**

**The glass ionomer cement to be used in the study is as follows:**

Resin-modified GIC is considered the standard against which test groups are being compared.[2]

1. Group 1- - Resin-modified GIC (GC Corporation, Tokyo, Japan ) -Control group
2. Group 2- GIOMER (Shofu Corporation) -Test group
3. Group 3- ZIRCONOMER (Shofu Corporation) -Test group
4. Group 4 - GIC type IX (GC Corporation, Tokyo, Japan) - Test group

**WORKFLOW**

a) **SAMPLE SIZE CALCULATION**

- The sample size calculation for ex-vivo study was done by using the data obtained from research conducted by Bhatia HP et al.[10]

- Sample size has been estimated based on statistical model called as Analysis of Variance, or ANOVA model. If we have k groups, then totally

  $K \equiv (k/2) = k(k-1)/2$ possible pair-wise comparisons will be possible.

  When we test $\tau \leq K$ of these pairwise comparisons, we have $\tau$ hypotheses of the form

  $H0 : \mu A = \mu B$; $H1 : \mu A < \mu B$ or $H0 : \mu A = \mu B$; $H1 : \mu A < \mu B$

  Where:

  $\mu A$ and $\mu B$ are means of two of the k groups, groups "A" and "B".

  We will calculate the sample size required for each of the $\tau$ comparisons.

  Total sample size required is the largest of these.

  In the formula below,

  N= sample size in any one of these $\tau$ comparisons; i.e. there are N/2 people in the "A"group, and N/2 people in the "B" group.

  Samples size will be calculated by using the formula:

$$N = \frac{2\,\sigma^2\,(Z_{1-\alpha/2\tau} + Z_{1-\beta})^2}{(\mu A - \mu B)^2}$$

  where,

$\kappa = nA/nB$ is the matching ratio = 1

$\sigma$ is standard deviation = 8.23

$\mu A$ is mean of Group "A" = 151.47

$\mu B$ is mean of Group "B" = 160.91

$\alpha$ is Type I error = 0.05

$\tau$ is the number of comparisons to be made = 6

$\beta$ is Type II error = 0.05 i.e. $1 - \beta$ is power = 95%

Substituting these values in above-mentioned formula, sample size estimated was N = 28 i.e. N/2= 14 samples per group are required.[14]

b) **PREPARATION OF TEST SPECIMENS EXCAVATION OF THE CARIES and STANDARDIZATION OF CAVITY-** Extracted human primary molars stored in 0.1% thymol solution will be included in the present in vitro study. Patients had given informed consent for use of extracted teeth for research study. Contra-angle hand-piece will be utilized to prepare Class II cavities in each tooth sample, only after cleaning the teeth. The dimensions of the cavities will be as follows:

**Width-3 mm, Depth-1.5 mm and Cervical margins 1 mm beneath the CEJ in dentine**, as verified by periodontal probe. [9]

c) **EVALUATION OF THE PHYSICAL PROPERTIES-** The following physical properties will be evaluated.

- **Measurement of Flexural strength** : Flexural strength will be determined by three-point bending test, The samples will be loaded in a three-point bending test device. The distance should be 10 mm among the supports. The samples will be placed with their edges equidistant from the midline of the mechanical testing machine. The cross-headspeed will be set at 0.5 mm/minute. The universal testing machine will measure the force during bending as a function of deflection of the beam.[3,11]
- **Measurement of Compressive Strength:** For the compressive strength testing, samples will be placed between the plates of the Instron Universal testing machine. This will be followed by application of compressive load on the specimens. Universal testing machine will be utilized to test the tooth samples and the loading rate will be 0.5 mm/minute.[10,11, 12]
- **Measurement of Wear resistance:** Samples of primary teeth with restorations will be checked for wear resistance with the help of Two-body wear tester. Logically programmed controlled equipment will be used to test two body wear of selected tested materials. Wear will be calculated after evaluating weight loss from initial weight and weight after subjecting to wear.[13]
- **Measurement of Microleakage/ Marginal integrity** : For evaluation of marginal integrity samples i.e. primary teeth will be thermocycled after immersing in distilled water for one day. Application of nail polish with double coating will be done at least I mm short of restorative margins. Bucco-lingual sectioning of samples will be done after storing in 2% methylene blue for a day. After removal, rinsing for 30 seconds in tap water, and drying, the sectioned halves of the teeth will be evaluated for dye penetration under a stereomicrosope. Values will be recorded on a scoring card.[1]

- **Fluoride estimation**: After initial setting of the glass ionomer restoration the samples will be stored in 100 mL of deionized distilled water at 37°C. Fluoride ion release will be estimated without changing the water at three intervals of 24 hours, 14 days and 28 days with Orion ion analyser.[4]

## FLOWCHART OF METHODOLOGY

Extracted primary molar teeth with 1 or 2 surface caries will be collected within inclusion criteria and used in the present study

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Subsequent cleaning and randomization of the extracted primary teeth will be done and code will be assigned. All the primary teeth will be randomly assigned into 4 groups of 2 samples each.

| Group 1 | Group 2 | Group 3 | Group 4 |
|---|---|---|---|
| Control group | Test group | Test group | Test group |
| Resin Modified-GIC | Giomer | Zirconomer | Type IX GIC |

↓

All the primary teeth will be disinfected by immersing the specimens in the hydrogen peroxide solution for one week. Teeth will be cleaned using ultrasonic scaler and stored in normal saline solution at room temperature until used.

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This will be followed by caries excavation, cavity preparation using No. 330 round bur. All tooth preparations were performed by the same operator to reduce variability

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Restoration with GIC type IX, Zirconomer, Giomer in the test group and Resin-modified GIC and Samples will be stored in **artificial saliva** having a pH of 7.0 and maintaining a temperature of 37 $^{0}$C until testing at 1 and 30 days. Refreshing of artificial saliva will be done after a week.

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**Fluoride ion release evaluations** will be evaluated after 24 hours, 14 days and 28 days respectively with the help of a ORION ion analyser

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Samples will be evaluated for **strength i.e. compressive and flexural strength** with the help of Universal testing machine -INSTRON.

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**Wear resistance**- It will be recorded with the help of 2 BODY WEAR TEST.

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**Marginal integrity**- Microleakage of samples will be assessed using a stereomicrosope.

**STATISTICAL ANALYSIS**

Data will be compiled and analyzed using SPSS v26 software. Level of significance will be kept at 5%. Data will be subjected to normality testing using Shapiro wilk test and depending upon the results of normality testing, appropriate statistical test will be applied to carry out comparisons. Continuous data will be presented using mean and standard deviation. Ordinal categorical data will be presented using frequency and percentage.

Intra-group comparison of change in fluoride levels within each group over different time intervals will be carried out using wither repeated measure ANOVA test or Friedman test followed by pairwise comparisons. Comparison of wear resistance, compressive strength, flexural strength, marginal leakage and fluoride release among four groups will be carried out using either One-way ANOVA test or Kruskal Wallis test followed by pairwise comparisons.[13]

**EXPECTED TIME DURATION FOR THE PRESENT RESEARCH**

The research study will be started after IEC approval and is expected to be completed within **14 months.**

| PROPOSED RESEARCH WORK | ESTIMATED TIME REQUIRED |
|---|---|
| Time required for collection of samples | 6 months |
| Time required for the preparation of samples and Evaluation of physical properties | 3 months |
| Time required for the analysis of the results and statistical evaluation | 2 months |
| Time required for scientific paper writing | 3 months |

**ESTIMATED BUDGET OF THE PRESENT RESEARCH WORK**

The tentative expenditure of the proposed research work is as follows:

**Expected cost of the dental materials-** **Rs 30,000/-**

**Expected cost of dental equipments-** **Rs 10,000/-**

**Expected Laboratory charges-** **Rs 70,000/-**

**Expected cost of stationary-** **Rs 10,000/-**

**Expected cost of transportation of samples** **Rs 50,000/-**

**Miscellaneous charges including and statistician assistance-** **Rs 35,000/-**

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**Total** **Rs 2, 05, 000/- (Approx)**

The research will be conducted with grant/ partial grant which have been approved from Indian Society of Pedodontics and Preventive Dentistry as a part of their '**ISPPD Research Assistance Grant scheme'** for its members.

**IMPLICATIONS OF THE PRESENT RESEARCH**

A dataset generated from this study will help to understand the following for pediatric patients in Indian sub population:

1. The study might provide vital information to pediatric dental surgeons on physical and mechanical properties of novel dental materials.
2. The results might help in selecting the appropriate restorative material clinically and scientifically
3. The results of the present study will also help guide the pediatric dental professionals in considering viable options for use in stress bearing areas in pediatric patients.
4. The results will help validate physical properties of modified GIC in deciduous teeth, and serve as reference datasets, beneficial both at national and international level.

5. The proposed study is expected to provide benefits to both the profession and the child patients.

**LIMITATIONS OF THE PRESENT STUDY:**

1. Selection of appropriate specific sample which is one of the essential determinants to validate physical properties of restorative material may not be practically possible.
2. Lack of specifications and standardization might become a limiting factor, if not properly followed.
3. There may be researcher's bias associated with the study.

**CONFLICT OF INTEREST**

Not applicable

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ORIGINALITY REPORT

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SIMILARITY INDEX

PRIMARY SOURCES

| | | |
|---|---|---|
| 1 | www.bio-forum.net<br>Internet | 97 words — 4% |
| 2 | Tsopmo, Gaston. "Foreign Direct Investment (FDI) and Economic Development in Sub-Sahara Africa: The Case Example of the Heavily Indebted Poor Countries (HIPC) Initiative in the Cameroon Republic and other Central Africa Countries.", Northcentral University<br>ProQuest | 30 words — 1% |
| 3 | www.njlm.net<br>Internet | 14 words — 1% |
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| 5 | Márjully Eduardo Rodrigues da Silva, Marcelle Danelon, José Antonio Santos Souza, Dinah Fressato Silva et al. "Incorporation of chlorhexidine and nano-sized sodium trimetaphosphate into a glass-ionomer cement: Effect on mechanical and microbiological properties and inhibition of enamel demineralization", Journal of Dentistry, 2019<br>Crossref | 11 words — < 1% |
| 6 | R., Sreedevi C.. "A Comparative Evaluation of Shear Bond Strength and Microleakage of Bulk-Fill Composite with Activa Bioactive Restorative Material on | 11 words — < 1% |

Extracted Permanent Teeth: An Ex Vivo Study", Rajiv Gandhi University of Health Sciences (India), 2023

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